SEP 2 3 2005



**510(k) Summary**

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| Name of Firm: | Synthes Spine<br>1302 Wrights Lane East<br>West Chester, PA 19380 |
| 510(k) Contact: | Angela Mikroulis<br>Spine Regulatory Affairs Specialist<br>Telephone: 610-719-5718<br>Facsimile: 610-719-5102 |
| Trade Name: | Pangea ™System |
| Common Name/<br>Classification Name: | Spinal interlaminal fixation orthosis;<br>Spinal intervertebral body fixation orthosis;<br>Pedicle screw spinal system |
| Device Product<br>Code and<br>Classification: | KWP, KWQ, MNH, MNI, NKB<br>21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070<br>CLASS II and Class III |
| Predicate: | Click'X (K992739) |
| Device Description: | The Pangea™ System is similar to the cleared Click'X (K992739). Both are components of the Universal Spinal System (USS).<br><br>The Pangea System includes polyaxial dual-core screws and a non threaded quarter turn in design locking cap.<br><br>The Synthes Pangea polyaxial screws and locking cap are fabricated from commercially pure titanium and titanium alloy, conforming to ASTM F67 and ASTM F-1295 respectively. |

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| Intended Use / Indications for Use: | The Synthes USS (including the Click'X®, and USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.<br><br>When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.<br><br>When used with the 3.5/6.0 mm parallel connectors, the Synthes USS (including the Click'X® and, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial and Dual-Opening USS can be linked to the CerviFix® System. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X®, and USS VAS variable axis components, and Pangea™), the Click'X® Monoaxial and Dual-Opening USS Systems.<br><br>In addition, Synthes USS (including the Click'X®, and USS VAS variable axis components, and Pangea™), Click'X® Monoaxial and the Dual-Opening USS can be interchanged with all USS 6.0 mm rods and transconnectors. |

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K052123

Device Name: Pangea ™

Indications for use: The Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0 mm parallel connectors, the Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial and Dual-Opening USS can be linked to the CerviFix® System. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), the Click'X® Monoaxial and Dual-Opening USS Systems.

In addition, Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial and the Dual-Opening USS can be interchanged with all USS 6.0 mm rods and transconnectors.

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| Prescription Use __X_____<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K052123